REMARKS/ARGUMENTS

Claims 1-3, 7-28 and 31-33 are currently pending. Claims 1-3, 6-29 and 31-33 stand rejected. Claims 6 and 29 have been canceled. Claim 30 has been objected to by the Office. Claims 1, 18 and 26 have been amended for clarity and no new matter has been added. No new claims have been added. Applicants respectfully request reconsideration.

Rejection of Claims 1-3, 6-29 and 31-33 under 35 U.S.C. § 103(a)

Claims 1-3, 6-29 and 31-33 stand rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Williams (U.S. Pat. No. 5,429,582; hereinafter referred to as "Williams") in view of Tam et al (U.S. Pat. No. 6,458,069; hereinafter referred to as "Tam"). In order to support a rejection under 35 U.S.C. § 103(a), the rejected claims must be obvious in light of the cited reference. Because Applicants' claims 1-3, 6-29 and 31-33 are not obvious in light of Williams in view of Tam, Applicants traverse these rejections, at least for the following reasons.

Applicants have amended independent claims 1, 18 and 26 to clarify and recite, in relevant part, that the "....treatment agent is releasably mated with an outer surface of the expandable surface member..." Support for this amendment can be found in Applicants' specification, at least, in paragraphs [0007], [0033], as well as in FIGS. 4A and 5. Claims 6 and 29 have been canceled because the limitations of former dependent claims 6 and 29 have been incorporated into amended independent claims 1 and 26, respectively. Therefore, the rejections of claims 6 and 29 are now moot.

Applicants' amended claim 1 recites,

> A drug eluting brachytherapy device, comprising:
> (a) an insertion member having a proximal portion, a distal portion, and at least one lumen extending therethrough;
> (b) an expandable surface member mated to the distal portion of the insertion member and defining a spatial volume therein, wherein said spatial volume is configured to receive a radiation source therein to enable a three-dimensional isodose profile that is substantially similar in shape to said expandable surface member; and
> (c) a treatment agent releasably mated with an outer surface of the expandable surface member; wherein at least a portion of the treatment agent is delivered to adjacent tissue when the brachytherapy device is positioned within a tissue cavity.

Applicants' amended claim 18 recites,

> A drug eluting tissue positioning device for positioning target tissue surrounding a resected tissue cavity so that the target tissue can receive a measured radiation dose, comprising:

a catheter body member having a proximal portion and a distal portion;

an expandable surface member, the expandable surface member defining a spatial volume therein, wherein said spatial volume is configured to receive a radiation source therein; and

a treatment agent releasably mated with an outer surface of the expandable surface member; wherein at least a portion of the treatment agent is delivered to tissue surrounding the resected tissue cavity when the device is positioned within the resected tissue cavity.

Applicants' amended claim 26 recites,

A method of delivering a treatment material, comprising:

providing a drug eluting brachytherapy device having a catheter body member with a proximal portion and a distal portion, an expandable surface member defining a spatial volume, and a treatment agent releasably mated with an outer surface of the expandable surface member;

positioning the brachytherapy device within a tissue cavity; and

delivering the treatment agent to tissue surrounding the tissue cavity.

Williams does not disclose "...a treatment agent releasably mated with an outer surface of the expandable surface member." as disclosed by Applicants' amended claims 1, 18 and 26. Williams discloses a completely implantable apparatus for treatment of tissue surrounding a cavity left by surgical removal of a brain tumor. See Abstract. A treatment fluid receptacle is provided for receiving a transdermal injection of a treatment fluid. A catheter means is connected between the receptacle and the balloon for carrying the treatment fluid from the receptacle means to the inflatable balloon. See col. 2, lines 7-16. Williams goes on to teach a balloon or distensible reservoir where the balloon is subsequently filled with fluid so as to substantially fill the cavity of the balloon. Williams goes on to recite that, "[t]he radioactive treatment fluid can be injected into the balloon 28 and left there for a prescribed period of time." (emphasis added) Because the treatment fluid is injected into the cavity of balloon taught by Williams, Williams does not teach a treatment agent on an outer surface of the expandable surface member. Because Williams does not teach a treatment agent on an outer surface of the expandable surface member, Williams certainly does not teach a treatment agent releasably mated with the outer surface of the expandable member. Applicants' amended claims 1, 18 and 26 are believed to be allowable, at least, because Williams does not teach or suggest "...a treatment agent releasably mated with an outer surface of the expandable surface member," as disclosed by Applicants' amended claims 1, 18 and 26.

Additionally, Tam does not disclose "...a treatment agent releasably mated with an outer surface of the expandable surface member," as disclosed by Applicants' amended claims 1, 18 and 26. Tam discloses a sealed radiation source, which may be used to deliver a radioactive

dose to a site in a body lumen. See Abstract. Preferably, the radiation source 10 is surrounded by an outer sleeve 38 (sometimes referred to as an encapsulant). See col. 21, lines 60-62 and FIG. 4. The radiation source is entrapped between the outer sleeve 38 and the balloon wall 36. See col. 21, lines 65-66 and FIG. 4. This is also illustrated in Tam at FIGs. 5, 6 and 7, wherein a radioactive source 10 is encapsulated between a balloon 36 and an outer encapsulant 38. The encapsulant 38 comprises an inner bonding surface 38b and an outer support layer 38a, both of which overlay radioactive source 10 as best shown in FIGS. 6 & 7. Because the radiation source 10 taught by Tam is sealed, entrapped or encapsulated within a number of different layers, Tam does not teach a treatment agent on an outer surface of the expandable surface member. Because Tam teaches a radioactive source 10 sealed, entrapped or encapsulated within a number of different layers, Tam certainly does not teach a treatment agent releasably mated with the outer surface of the expandable member. Applicants' amended claims 1, 18 and 26 are believed to be allowable, at least, because Tam does not teach or suggest "...a treatment agent releasably mated with an outer surface of the expandable surface member," as disclosed by Applicants' amended claims 1, 18 and 26.

Furthermore, Tam does not teach or suggest an expandable surface member configured to receive a radiation source therein. Applicants have amended independent claims 1 and 18 to clarify and recite, in relevant part, "...an expandable surface member... defining a spatial volume therein, wherein said spatial volume is configured to receive a radiation source therein...". Tam does not teach or suggest receiving a radiation source within the expandable surface member. As discussed above, Tam teaches a radioactive source 10 sealed, entrapped or encapsulated within a number of different layers of the wall. Because Tam does not teach or suggest an expandable surface member configured to receive a radiation source therein, Applicants' amended claims 1 and 18 are believed to be allowable over Tam.

Applicants respectfully assert that there is no motivation to combine the Williams and Tam references. Williams teaches a completely implantable apparatus for treating tissue surrounding a cavity left after surgical resection of a brain tumor, while Tam teaches delivery of a radioactive dose to a site in a body lumen. Williams teaches a subcutaneously implantable treatment fluid receptacle for receiving a transdermal injection of a treatment fluid. See Abstract. The radioactive treatment fluid taught by Williams can be injected into the balloon 28 and left there for a prescribed period of time and then it may be removed. See col. 5, lines 33-35. Tam teaches a continuous seal between the encapsulant, the radiation delivery layer, and the balloon along at least a length of the radiation delivery layer to provide a sealed source. See col. 5, lines 12-15. Because the treatment fluid taught by Williams can be injected and removed during treatment, while the radiation source taught by Tam is continuously sealed and

thus, not removable, Applicants respectfully assert that the Williams and Tam references teach away from one another. Because there is no motivation to combine the Williams and Tam references, Applicants' amended independent claims 1, 18 and 26 are believed to be allowable over the combined teachings of Williams and Tam. Applicants' dependent claims 2, 3, 7-17, 19-25, 27, 28, and 30-33 are believed to be allowable, at least, because they depend from allowable independent claims 1, 18 or 26. Applicants respectfully request that the rejection of claims 1-3, 6-29 and 31-33 be withdrawn.

Conclusion

In light of the above Remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case. If the Office should have any questions or other issues to discuss, please do not hesitate to contact the undersigned attorney.

Applicants believe a three month extension of time fee is required. Please consider this a request for a three month extension of time and charge Deposit Account No. 50-2855 accordingly. If any additional petitions or fees are necessary, please consider this a request therefore and authorization to charge Deposit Account No. 50-2855 accordingly. Any deficiency or overpayment may also be applied to Deposit Account No. 50-2855.

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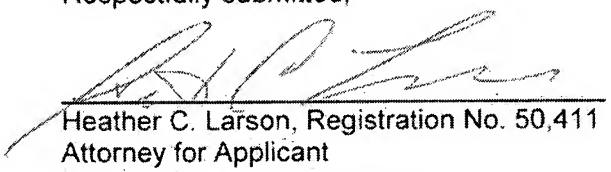
Respectfully submitted,



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